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10/672,833	09/26/2003	Mark Edward Riehl	NNI-0005	1330

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EXAMINER	
HOPKINS, CHRISTINE D	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/672,833	RIEHL, MARK EDWARD	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 30-69* is/are rejected.

7)☒ Claim(s) *29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/05, 11/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. The Office action mailed on 20 October 2006 has been reconsidered and the election of species requirement withdrawn. Claims 1-69 are currently pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "disposal mechanism" must be shown or the feature canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademark Kapton™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-19 and 54-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 7 and 54 at line 1 recite "a disposal mechanism that renders the circuit pad inoperable." However, the "disposal mechanism" disclosed by the instant specification is afforded no structural recitation, nor is such an element disclosed in the drawings.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 at line 4 recites the limitation "the conductor is adapted to reduce stimulation caused by the magnetic stimulation device" however the stimulation device is not a positively claimed element since the claims recites a system for reducing discomfort caused by a magnetic stimulation device.

Claim 42 contains the trademark/trade name Kapton™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a circuit pad

material and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-28, 30, 35-41, 43-51, 53-63 and 67-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al. (U.S. Pub. No. 2004/0122281). Fischell et al. (hereinafter Fischell) teach a system for generating a magnetic field into and around a user's head. Regarding claims 1 and 21, Fischell discloses a circuit pad **10** having at least one conductor **18A** located peripheral, and connected to, a magnetic stimulation device **15** (Fig. 3 and [0042]). Electronics module **13** includes circuitry that is in communication with the conductor [0040], in view of claim 2, but is further interpreted as a "connector" as recited in claim 6. Regarding claims 3-5, the "predetermined" location being stimulated is the head of the patient, relative to a treatment area such as the cerebral cortex [0020].

Regarding claims 7-10, and their indefinite nature, the hand belt **12** is interpreted as the "disposal mechanism". The disposal mechanism is "activated by a user" such that a patient utilizes it to hold the device to the head and/or neck, thus also being

capable of removal from the patient [0043]. Regarding claims 12-15, the "disposal mechanism is activated" after a predetermined number of uses by the user and permits the user to use the circuit pad for a specific period of time. The user may choose to place the device at a location found to be effective. In view of claims 11 and 16, removal of the "disposal mechanism" **12** renders the device unusable since the user can no longer place it in a treatment position. Regarding claim 17, "disposal mechanism" **12** is capable of being sanitized, or likewise, not being sanitized.

In view of claims 18-19, the circuit pad would become inoperable and would also be capable of disintegrating if placed in contact with certain cleaning solutions.

Regarding claim 20, the hand belt **12** is adapted to be attached to the patient [0041].

In view of claim 22, the Velcro holding strap taught by Fischell is considered to be an "adhesive" [0012].

With respect to claims 23-25, the flat, metallic conductor **18** is located between two surfaces of the circuit pad **10** (see Fig. 2). While the magnetic stimulation device **15** has a length between 5 and 15 cm and a width between 3 and 10 cm, the conductor **18** has a claimed range of 1 cm^2 to 40 cm^2 because of its dimensions being comparable to those of the magnetic stimulation device (see Fig. 2). The intensity of the time-varying magnetic field may be between 0.1 and 5 Tesla, and the frequency rate of the pulses varied between 0.1 Hz and 500 Hz, thus capable of reducing the stimulation created by the magnetic stimulation device in accordance with claim 26.

With respect to claim 27, the conductors **18** and the magnetic stimulation device **15** of the device of Fischell are both fully capable of creating magnetic fields [0042].

Regarding claims 28 and 30, the conductor **18** is provided electrical energy simultaneously with electrical energy provided to the magnetic stimulation device **15** [0042]. Electrical energy provided to the conductor is a current that is derived from a voltage provided to the magnetic stimulation device [0013].

In view of claims 35 and 38, the conductor is capable of being placed substantially orthogonal to an electric field vector created by the magnetic stimulation device **15**. The conductor **18** also has rounded edges considering it is of the configuration of a coil, in accordance with claim 36. Regarding claim 37, since Applicant does not disclose the conductor having a "high aspect ratio" and only that it may have a particular aspect ratio, the coil windings of Fischell, or conductors **18**, having a coiled configuration as **503a** and **503b** (of instant specification) anticipate the claimed "aspect ratio" of the instant application.

With reference to claims 39 and 41, the circuit pad is arc-shaped as evidenced by Fig. 3, and is constructed of a flexible material such that it conforms to the head or neck of a patient. In view of claim 40, the hand belt **12** serves as insulation to the flexible circuit pad **10**.

Regarding claim 43, the magnetic stimulation device comprises a magnetic core, such as a ferromagnetic core, that has a high saturation flux density [0042] with an intensity of the magnetic field at the surface of the brain between 0.1 and 5 Tesla [0047].

In view of claims 44, 46 and 49, Fischell teaches a method for treating a patient using TMS comprising directing a magnetic field created by a magnetic stimulation device **15** to the head and/or neck of a patient; applying a flexible circuit pad **10** comprising at least one conductor **18** adapted to reduce stimulation induced by the magnetic stimulation device and treating the patient with such. For instance, treating the trigeminal nerve requires a much lower level of current [0050]. Regarding claim 45, the magnetic stimulation device comprises a magnetic core, such as a ferromagnetic core, that has a high saturation flux density [0042] with an intensity of the magnetic field at the surface of the brain between 0.1 and 5 Tesla [0047].

With respect to claim 47, the flexible circuit pad **10** is applied to the magnetic stimulation device **15** such that both are in connection with each other (Fig. 3).

Regarding claim 48, while the specification does not provide adequate disclosure for a magnetic stimulation device having a magnetic core with a "non-toroidal geometry," it is understood by the plain definition of the term of "toroidal" to be "donut-shaped," and thus the core of the magnetic stimulation device **15** of Fig. 1 is "non-toroidal" and anticipates the claim.

In view of claims 50-51, the magnetic stimulation device is located to the treatment area of the patient as the patient places the circuit pad **10** on the area of the head or neck requiring treatment.

Regarding claim 53, the hand belt **12** serves as insulation to the flexible circuit pad **10**.

Regarding claims 54-58, and their indefinite nature, the hand belt **12** is interpreted as the "disposal mechanism". The disposal mechanism is "activated by a user" such that a patient utilizes it to hold the device to the head and/or neck, thus also being capable of removal from the patient [0043]. In view of claim 59, removal of the "disposal mechanism" **12** renders the device unusable since the user can no longer place it in a treatment position. Regarding claim 60, the "disposal mechanism is activated" after a predetermined number of uses by the user and permits the user to use the circuit pad for a specific period of time. In view of claims 61-62, the circuit pad **10** is adapted to be attached to the patient via hand hole **22** through which the patient attaches the pad to the area of treatment (see Fig. 4). In view of claim 63, the Velcro holding strap taught by Fischell is considered to be an "adhesive" [0012].

Regarding claims 67-69, Fischell teaches a circuit pad **10** having a ferrite material located peripheral to a magnetic stimulation device **15** and located between two surfaces of the circuit pad (see Fig. 3), and further adapted to the head and/or neck of a patient receiving treatment. Electronics module **13** includes circuitry that is in communication with the ferrite material ([0040] and [0042]).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 31-34, 42, 52 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Pub. No. 2004/0122281) in view of Henley et al. (U.S. Patent No. 6,477,410). Fischell discloses the invention as claimed, see rejection supra; however Fischell fails to disclose a conductive gel facilitating communication between the circuit pad and a treatment area. Henley et al. (hereinafter Henley) disclose a device for self-administration of medicament to a treatment site. Regarding claims 31-33, Henley teaches a conductive gel that facilitates electrical conduction between a treatment area and an electrode **30** of an applicator. The conductive gel may be provided within a porous, or "absorbent" substrate **42** of pad **44**. The porous substrate **42** is interpreted as a sponge material (col. 20, lines 48-61). In view of claims 34 and 42, the substrate may also be made of a plastic material, and shaped according to an individual's anatomy. Fischell, likewise, incorporates an assembly that conforms to the anatomy of an individual for treatment. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have introduced a conductive gel for delivering treatment to an individual as suggested by Henley to a device for reducing pain for an ailment to the head as suggested by Fischell, for providing increased contact between the device and the individual for effective treatment of the site of interest.

Regarding claims 52 and 64-66, Henley teaches that a conductive gel may be applied between the circuit pad and the patient (col. 20, lines 48-61). The substrate of the circuit pad may also be made of a plastic material, and shaped according to an individual's anatomy (col. 21, lines 31-39). Similarly, Fischell teaches constructing the

treatment assembly of materials that enable conformance to the anatomy of an individual. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have introduced a conductive gel for enabling better contact between a patient and a conductor as suggested by Henley to a device enabling specific treatment to a patient as taught by Fischell, to more effectively provide treatment at a particular area of interest on a patient.

Allowable Subject Matter

12. Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Regarding claim 29, while the prior art of record discloses a magnetic depolarizer for the treatment of the head and/or neck, it does not teach or fairly suggest electrical energy provided to the conductor and that to the magnetic stimulation device being of opposite polarities.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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